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10/029,981	12/31/2001	Toshinari Sakurai		6062

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicant(s)

10/029,981

Applicant(s)

SAKURAI ET AL.

Examiner

Francisco C Prats

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1651

**DETAILED ACTION**

The amendment filed December 31, 2001, has been received and entered.

Claims 1-9 have been cancelled.

Claims 15-20 have been added.

Claims 10-20 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Despite the fact that the preamble of each of claims 15-17 recites an apparatus, each of claims 15-17 recites a method step following the recitation of the elements of the apparatus. Specifically, claim 15 recites that "the apparatus is operated automatically by the program." This is confusing because the method step is not appropriate in the apparatus claim, since it is not clear how the method step can possibly provide a

Art Unit: 1651

structural modification or limitation to the claimed apparatus. Claim 15 and its dependents must therefore be considered indefinite.

Similarly claim 16 recites that the various elution solutions "are separately sucked and discharged into and from the pipette tip by means of the syringe pump." Again, however, these process steps cannot modify the claimed apparatus. Rather, these limitations are directed to methods of using the apparatus, and do not set forth any structural limitation for the apparatus.

Similarly, claim 17 recites that "the nozzle holder moves in response to a command to a position of tip rack where a plurality of pipette tips are dispensed." Again, this limitation prescribes a method of use, not a structural limitation, or even a functionally defined structural limitation. It is therefore confusing what structural limitations are required by the method-of-use language set forth in these apparatus claims. Claim 20 similarly contains such a method-of-use limitation in the apparatus claim.

Lastly, claim 18 is considered indefinite because, despite the Jepson-type preamble ("In an apparatus . . ."), the claim does not state that the limitation prescribed therein is an improvement. Because it is not clear whether applicant intends

Art Unit: 1651

to recite a Jepson claim, a holding of indefiniteness is therefore required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Petschek et al (U.S. Pat. 5,389,339).

Petschek discloses a computer-controlled automated system for the purification of DNA from biological samples. Petschek's apparatus comprises a syringe pump as required by claim 16. See column 2, lines 61-65:

The means for withdrawing fluid from the sample tubes preferably includes an air cylinder operably connected to the pipet arm pipetting end. The air cylinder may include a movable piston for varying the volume of the air cylinder . . . .

Note specifically that a pump containing a "movable piston" anticipates the "syringe pump" recited in applicant's claims. See also figure 2A, item 16a, clearly disclosing a syringe pump.

Figure 2A of Petschek also discloses the movable nozzle connected via a pipe to the syringe pump. See also Fig. 1B, disclosing the movable nozzle and holder, item 58, as well as the elongated pipette tips, items 80 and 81, which may be detachably connected to the nozzle. Note that Petschek is considered to meet the process limitations requiring fluid sample sucking and discharging in claims 16 and 17, based on the fact that Petschek's apparatus clearly is capable of performing these tasks, as well as being able of enclosing a solid phase containing silica. A holding of anticipation over the cited claims is clearly required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to

Art Unit: 1651

point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopaciewicz (U.S. Pat. 6,048,457).

Kopaciewicz discloses processes a pipette tip containing silica. See, e.g., Examples 1-11. Kopaciewicz differs from the claims in not using the silica in the form of quartz wool. However, Kopaciewicz clearly discloses that virtually any form of silica can be used, including "shards" and "fibers". See column 4, lines 54-59. Thus, by clearly suggesting the use of fiber-containing forms of silica, Kopaciewicz clearly suggests the use of quartz wool, which contains silica fibers, for use in the pipette tips disclosed therein. A holding of obviousness is therefore required.

Claims 10-15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al (U.S. Pat. 5,389,339) in view of Kopaciewicz (U.S. Pat. 6,048,457)).

As discussed above, Petschek discloses a computer-controlled automated system for the purification of DNA from biological samples. Petschek differs from the cited claims in

Art Unit: 1651

that Petschek does not employ the use of silica-containing pipette tips as recited in the claims.

However, Kopaciewicz discloses that the silica-containing pipette tips disclosed therein are suitable for use in the preparation of DNA from biological samples. See Examples 14, 15 and 17, at cols. 13 and 14. Advantages of the silica-containing pipette tips disclosed by Kopaciewicz include the ability to purify desired products from very small samples, as well as simplicity and economy of manufacture. Thus, the artisan of ordinary skill, recognizing from Kopaciewicz the advantageousness of silica-containing pipette tips, clearly would have been motivated to have used those pipette tips in the automated apparatus of Petschek, reasonably expecting that the advantages of the silica-containing would be conveyed to Petschek's apparatus. A holding of obviousness is therefore required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner



Application/Control Number: 10/029,981


Page 8

Art Unit: 1651

can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP